

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF MISSOURI  
CENTRAL DIVISION**

<b>EARL RINGO, et al.,</b>	)	
	)	
<b>Plaintiffs,</b>	)	
	)	
<b>vs.</b>	)	<b>No. 09-4095-CV-C-NKL</b>
	)	
<b>GEORGE A. LOMBARDI, et al.,</b>	)	
	)	
<b>Defendants.</b>	)	

**Reply to Defendants’ “Reply to Plaintiff’s Supplemental Suggestions”  
Concerning Cross-Motions for Summary Judgment**

For the first time in these proceedings, Defendants advance a novel argument that their protocol actually conforms with federal law, so that compliance with both is not “impossible” for purposes of preemption. *See* “Reply to Plaintiff’s Supplemental Suggestions,” (ECF Doc. 259), at 3-4. Defendants cite a regulation under the Controlled Substances Act, which permits an individual practitioner to “administer or dispense directly a controlled substance without a prescription.” ECF Doc. 259, at 3, citing 21 C.F.R. § 1306.11(b). Defendants argue that the definition of “administering” a drug under the CSA includes “the direct application of a controlled substance by a practitioner, or in his presence by his authorized agent.” *Id.*, citing 21 U.S.C. § 802(2)(a). Therefore, the argument goes, DEA-registered physician M3 may, without issuing a prescription, freely administer the controlled substance sodium thiopental by watching his non-

medical supervisee inject the drug. ECF Doc. 259, at 3-4. Defendants essentially liken their protocol to what happens in hospitals or doctors' offices, when a nurse might give narcotic pills to a patient under a physician's direction and supervision.

Defendants are wrong. They neglect to mention essential qualifying language within the regulation they cite:

An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II ***in the course of his professional practice*** without a prescription

21 C.F.R. § 1306.11(b) (emphasis added).<sup>1</sup> The defense-omitted language is not mere surplusage. It is essential to the statutory and regulatory scheme of the CSA, which makes it unlawful for medical practitioners to dispense and administer controlled substances “when their activities fall outside the usual course of professional practice.” *United States v. Moore*, 423 U.S. 122, 124 (1975); *United States v. Kanner*, 603 F.3d 530, 533 (8th Cir. 2010). The regulation parallels statutory language underlying these precedents. *See* 21 U.S.C.A. § 802(21) (“practitioner” is a professional licensed to dispense, administer, or distribute controlled substances “in the course of professional practice or research”); *Moore*, 423 U.S. at 141-42.

The point is that a licensed practitioner may not rely on just any “agent” to medicate a patient with controlled substances. Rather, the drug must be dispensed

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<sup>1</sup>Plaintiffs will simply assume, *arguendo*, that the regulation applies as fully to Schedule III controlled substances as to those under Schedule II.

or administered in accordance with “a standard of medical practice generally recognized and accepted in the United States.” *Moore*, 423 U.S. at 139; *United States v. Smith*, 573 F.3d 639, 646-49 (8th Cir. 2009); *United States v. Armstrong*, 550 F.3d 382, 399 (5th Cir. 2008). Otherwise stated, “[A] licensed practitioner is not immune from the act solely due to his status, . . . but rather, because he is expected to prescribe or dispense drugs within the bounds of his professional practice of medicine.” *United States v. Collier*, 478 F.2d 268, 271-72 (5th Cir. 1973). From this principle flows the restriction that a non-registered supervisee may not administer controlled substances unless permitted to do so by the jurisdiction in which he or she practices. *See* Drug Enforcement Administration, Office of Diversion Control, Practitioner’s Manual: An Informational Outline of the Controlled Substances Act (2006) (available at [http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract\\_manual\\_012508.pdf](http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual_012508.pdf)), at 28.

Missouri’s protocol fails these requirements. It involves a controlled substance administered for a medical purpose – and yet in a manner that is utterly foreign to accepted medical practice: a non-medical prison employee administers sodium thiopental through an IV-push. Quite unlike the act of a nurse handing off a pill, the IV-push of anesthesia is a highly specialized medical procedure in which the practitioner must rely on clinically-acquired “visual and tactile cues” to ensure that the drug is properly administered so that it actually sedates the patient. *See*

Plaintiffs' Opposition Ex. D (Affidavit of Dr. Heath), at 5-6; Plaintiffs' "Statement of Additional Material Undisputed Facts" ¶¶ 11-15 (ECF Doc. 226, at pp. 7-9).

The protocol is a stark deviation from the accepted practice of administering anesthesia, and Defendants present no evidence to the contrary. *Id.* We also know that Missouri law does not permit an IV-push to be performed even by Nurse M2, much less by non-medical prison employees.<sup>2</sup> And we know that the protocol departs from anesthesiologist M3's own medical practice, in which anesthesia is always administered by M3 himself or by the *anesthesia specialists* he is supervising. *See* Plaintiffs' Ex. 5 (also Def. Ex. 2) (M3 Depo.), at 81, 123.

Defendants, then, find no refuge in 21 C.F.R. § 1306.11(b), or in their attempt to launder the administration of a controlled substance through an "agent" whose very actions are anathema to the accepted practice of medicine. Finally, even if their novel argument were somehow sufficient for compliance with the CSA, it does not even mention the Food, Drug, and Cosmetic Act or its independent preemptive effect. Plaintiffs remain entitled to summary judgment.

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<sup>2</sup>*See* Plaintiffs' Ex. 3 (also Defendants' Ex. 1) (M2 Depo.), at 162-63; 20 Mo. CSR § 2200-6.030(7)(G) ("Graduate practical nurses and licensed practical nurses shall NOT, under any condition . . . [a]dminister drug(s) via the intravenous push or intravenous bolus mode of delivery except when life-threatening circumstances require such administration."); Mo. Rev. Stat. §§ 334.104.2, 334.104.7, 334.402.1, 334.424.1; 20 Mo. CSR §§ 2150-9.040, 2200-4.200.3(G)(9) (providing only for administration by anesthesiologist, a nurse anesthetist, or a licensed anesthesiologist assistant, other than in dental or veterinary settings).

Respectfully submitted,

/s/ Joseph W. Luby

Joseph W. Luby, Mo. 48951  
Public Interest Litigation Clinic  
6155 Oak Street, Suite C  
Kansas City, MO 64113  
816-363-2795 • FAX 816-363-2799  
*Counsel for Plaintiff Winfield*

Jennifer Herndon, Mo. 37921  
224 Hwy 67 North, # 122  
Florissant, Mo 63031  
314-831-5531 • FAX 314-831-5645  
*Counsel for Plaintiffs Nunley,  
Ferguson, Clay, Nicklasson,  
and Franklin*

David Barron, Ky. Bar 90269  
100 Fair Oaks Lane, Suite 301  
Frankfort, KY 40601  
502-564-3948 • FAX 502-564-3949  
*Counsel for Plaintiffs Ringo, Bucklew,  
Middleton, and Winfield*

Michael J. Gorla, Mo. 26399  
720 Olive Street, Ste. 1630  
St. Louis, MO 63139  
314-621-1617  
*Counsel for Plaintiff Ferguson*

John William Simon, Mo. 34535  
Constitutional Advocacy, L.L.C.  
7413 Manchester Road, Suite 109  
St. Louis, MO 63143  
314-604-6982 • FAX 314-754-2605  
*Counsel for Plaintiffs Bucklew,  
Middleton, and Michael Taylor*

Christopher E. McGraugh, Mo 36301  
Leritz, Plunkert & Bruning  
555 Washington Avenue, Suite 600  
St. Louis, MO 63101  
314-231-9600 • FAX 314-231-9480  
*Counsel for Plaintiff Link*

Cheryl Ann Pilate, Mo. 42266  
Rebecca L. Kurz, Mo. 40451  
Morgan Pilate LLC  
142 North Cherry  
Olathe, KS 66061  
913-829-6336 • FAX 913-829-6446  
*Counsel for Plaintiffs Bucklew, Middleton,  
Ringo, and Smulls*

Elizabeth Unger Carlyle, Mo. 41930  
P.O. Box 30418  
Kansas City, MO 64112  
816-525-6540 • FAX 866-764-1249  
*Counsel for Plaintiffs Clay, Barnett,  
Clayton, and Leon Taylor*

Eric W. Butts, Mo. 36184  
720 Olive Street, Suite 1630  
St. Louis, MO 63101  
314-621-1617 • FAX 314-621-7448  
*Counsel for Plaintiffs Christeson  
and Rousan*

## **CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing was forwarded for transmission via Electronic Case Filing (ECF) this 18th day of July, 2011, to Andrew W. Hassell, Michael J. Spillane, and Stephen D. Hawke, Office of the Attorney General, P.O. Box 899, Jefferson City, Missouri 65101.

/s/ Joseph W. Luby  
Joseph W. Luby

*Counsel for Plaintiff John E. Winfield*